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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/855,287      | 05/15/2001  | Arthur C. Coffey     | 7175-67882          | 1909             |

7590 12/15/2003

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| EXAMINER |
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CHANNAVAJALA, LAKSHMI SARADA

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 12/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/855,287

Applicant(s)

COFFEY, ARTHUR C.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-9,14-18,27,28,30-37 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-9,14-18,27,28,30-37 and 39-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt of amendment C dated 6-19-03 is acknowledged.

Claims 1, 2, 6-9, 14-18, 27, 28, 30-37 and 39-45 are pending.

Applicant's arguments with respect to claims 1, 2, 6-9, 14-18, 27, 28, 30-37 and 39-43 have been considered but are moot in view of the new ground(s) of rejection.

#### *Claim Rejections - 35 USC § 103*

Claims 1, 2, 8, 9, 14-18, 27, 28, 30-37 and 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,645,081 to Argenta in view of US 4,841,962 to Berg et al (Berg).

Instant claims are directed to a wound care bandage comprising a collagen matrix, a cover to seal the wound that is adapted for communication with a vacuum source, and a structure for placement between the collagen matrix and the wound cover. The collagen matrix in the instant claims is placed on the wound surface and integrates upon placement into the wound.

Argenta teaches a method of treating tissue damage in burns and wounds (abstract, col. 1, lines 55-65). The apparatus of Argenta comprises a vacuum means for creating a negative pressure on the area of tissue surrounding the wound, sealing means operatively associated with the vacuum means to maintain negative pressure on the wound and a screen means to prevent overgrowth of tissue in the wound area. The screen means comprises a section of open-cell foam, which is porous, configured to be placed over a wound, into which is inserted a flexible tube for attachment to a suction pump. The sealing means comprises a polymeric sheet above the foam section and tubing such that it is adhered to the skin surrounding the wound (col. 2, lines 15-28). Argenta teaches that the screen means is a semi-rigid structure and is directly connected to the vacuum source (col. 4, lines 29-60) and the screen means reads on the instant structure placed

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between the collagen matrix and the cover. Argenta teaches application of pressure in cycles in alternate periods of application and non-application (col. 3, lines 9-18). Further, Argenta teaches that the method of applying negative pressure enables increased blood flow into the wound area, reduces the bacterial infection in the area and thus enhances wound healing and (col. 3, lines 29-46), which is also claimed in the instant method claims.

Argenta lacks a collagen layer in contact with the wound, as in the instant claims.

Berg et al teaches a wound dressing comprising a collagen matrix and polymer film for absorbing fluids while remaining secured to the wound, protecting the wounds from moisture loss, bacterial contamination, reinjury and skin maceration (col. 4, line 19-21). Berg teaches that the collagen matrix provides epithelial and fibroblast cells in the wound bed with a scaffold on to which to they attach and grow, thus providing migration and angiogenesis facilitated by bioabsorbable wound dressing. Berg also state that even after removing the wound dressing some of the collagen remains in the wound bed permanently which continues to aid healing (col. 7, lines 51-61). Thus, it is implicit that the collagen matrix of Berg is integrated into the wound.

Both Argenta and Berg recognize the importance of a collagen matrix at the site of wound, which provide an attachment site and allow for migration and growth of cells thus leading to proper wound healing. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add collagen matrix of Arnold in the vacuum assisted therapy for wound healing of Argenta because Berg teaches that collagen absorbs wound exudates and also acts as a slow relelease matrix for the relelease of wound (col.2) because of its scaffold structure provides a natural attachment site for healing cells. Accordingly, by placing one or several layers of collagen in the structure of Argenta, an ordinary skill in the art would

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have expected to relelase the fibroblast growth factor or other wound healing promoting and infection reducing agents to release from collagen matrix for a sufficient period of time so as to ensure complete and thorough healing of the wound. Further, upon applying vacuum one of an ordinary skill in the art would have expected the exudates (including blood) to draw from wound in to collagen and that collagen integrates in to the wound over a period of time. Further, while neither reference teach the specific ring shaped structure of claims 14 and 32, Argenta teaches the same porous material and for the same purpose i.e., absorb exudates. Therefore, using an appropriate shaped structure of the pad, without altering the recognized function would have been within the scope of a skilled artisan.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,645,081 to Argenta in view of US 4,841,962 to berg et al (Berg) as applied to claims 1, 2, 8, 9, 14-18, 27, 28, 30-37 and 39-45 above, and further in view of US 6,440,427 to Wadstrom.

The wound dressings of Argenta and Berg, discussed above, do not contain instant fibrin glue for holding collagen matrix.

Wadstrom teaches tissue treatment composition comprising fibrin or fibrinogen, and biodegradable polymers for wound healing or slow-release drug formulations etc (col. 1, lines 12-15). Wadstrom teaches fibrin is a known biological adhesive and is mixture of fibrin and thrombin that forms a coagulum (col. 1, lines 23-30). Wadstrom teaches fibrin sealants act in several ways, in hemostasis, glueing and wound healing. Further, Wadstrom teaches that fibrin sealants are used in a number of fields, especially for wound healing and prevention of adhesion of adjacent tissues (col. 3, lines 37-48).

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It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the fibrin sealant of Wadstrom in the wound dressing of Argenta, containing collagen of Berg because Wadstrom suggests that fibrin glue, due to its adhesive properties, is capable of atraumatically connecting tissues by forming a strong joint between them and adapts uneven wound surfaces, promotes the growth of fibroblasts, which in combination with efficient hemostasis and adhesion between the wound surfaces provides for an improved healing process. Further, Wadstrom teaches that the fibrin glueing effect is increased by fibronectin binding to exposed collagen (col. 1, lines 57 through col. 2, lines 15). Accordingly, one of an ordinary skill in the art would have expected to increase the homeostasis and fibroblast growth at the wound-healing site, by placing fibrin glue close to the collagen layer in the wound dressing of Argenta.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
December 10, 2003



THURMAN K PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600